Remarks

Claims 1-31 are pending in this application. Claims 1, 12, and 24 have been amended, and no claims have been added or canceled. Reconsideration of this application is respectfully requested in light of the above amendments and the following remarks.

Rejection of Claims 1-3, 6, 10, and 12
Under 35 U.S.C. § 102(e) Over Clayton

Claims 1-3, 6, 10, and 12 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,197,044 issued to Clayton ("Clayton"). In response, Applicants have amended independent claims 1 and 12 to more particularly point out and distinctly claim the subject matter of the invention.

Specifically, Applicants have amended claim 1 to recite that "the inlet opening is sized for connection to a standard breathing tube" and amended claim 12 to recite that the proximal end of the connector has "an outer diameter of approximately 15 mm for compatibly attaching to a standard breathing tube." Applicants explain that the proximal end of the connector is sized to provide compatible attachment to a standard external breathing tube (*see* p. 4, lines 10-12; p. 7, lines 23-30), wherein breathing tubes have standard U.S. and international dimensions as is known to those skilled in the art. Therefore, once a child has Applicants' medical pacifier in place in his/her mouth, a standard anesthesia breathing circuit can be quickly and easily attached to the pacifier (*see* p. 8, lines 18-31).

In contrast, Clayton discloses a device for administering oral fluids to infants, wherein the nipple has an inner lumen which may removably receive a tube therein, specifically a feeding or medication tube (*see* Abstract; col. 2, lines 18-34). Clayton does not disclose or suggest that any part of her pacifier is "sized for connection to a standard breathing tube" as disclosed and claimed by Applicants. As explained by Applicants, the pacifier must be capable of receiving the breathing tube so that a tight seal is formed in order to prevent anesthesia gas from escaping at the interface (*see* p. 8, lines 27-31), thus requiring specific sizing of the inlet opening or connector to ensure a secure connection.

Therefore, Applicants believe that claims 1 and 12, as amended, overcome the rejection thereof over Clayton. Accordingly, reconsideration and withdrawal of the rejection of these claims, along with their corresponding dependent claims, under 35 U.S.C. § 102(e) is respectfully requested.

Rejection of Claims 24-25, 28-29, and 31
Under 35 U.S.C. § 102(b) over Hinkle

Claims 24-25, 28-29, and 31 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,896,666 issued to Hinkle ("Hinkle"). Although Applicants respectfully disagree with the Examiner's characterization of the Hinkle reference, Applicants have amended independent claim 24 to more particularly point out and distinctly claim the subject matter of the invention.

Specifically, claim 24 has been amended to recite "supplying gas through the base and the nipple member for delivery via the outlet opening *exclusively* into the oral cavity of the patient" (emphasis added). As is understood by those skilled in the art, anesthesia and other gases inhaled via the nasal passages are naturally filtered, thereby reducing the amount of gas which reaches the lungs of the patient over a given time. This may result in a longer time required for inhalation therapy to be performed, and possibly less consistent and less efficacious outcomes (*see* p. 2, line 30 - p. 3, line 10).

In contrast to Applicants' claimed invention, Hinkle discloses that "anesthetic gas can be introduced through the opening 28 where it will pass through passageway 34 of the pacifier through apertures 38 into the air space 22 so that the wearer can breathe the gas through the nose" (*see* col. 4, lines 57-61). In fact, the only use that Hinkle discloses for hole 36 at the tip of pacifier 12 is that "a catheter can be inserted through opening 28 of the mask and through passageway 34 so that the end of the catheter is positioned between the apertures 38 and hole 36 and suction can be provided through hole 36" (*see* col. 4, line 65- col. 5, line 1).

Therefore, Applicants believe that claim 24 overcomes the rejection thereof under 35 U.S.C. § 102(b) over Hinkle. Accordingly, Applicants respectfully request

reconsideration and withdrawal of the rejection of this claim and corresponding dependent claims 25, 28-29, and 31.

Rejection of Claims 4-5, 7, 9, 11, 13-20, and 22-23
Under 35 U.S.C. § 103(a) over Clayton

Claims 4-5, 7, 9, 11, 13-20, and 22-23 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton. With reference to claim 13, Applicants respectfully traverse this rejection. As explained above regarding claims 1 and 12, Clayton discloses a device for administering oral **fluids**, such as breast milk, formula, or medication, to infants, and does not disclose or suggest use of her pacifier for gas delivery. Clayton does not recognize the problem solved by Applicants claimed invention, namely providing a pacifier which can be quickly and securely connected to a standard breathing tube for delivering gases to a patient via the oral cavity. Applicants have explained that a specific pacifier construction is required for suitable connection to a standard breathing tube and circuit, and Clayton clearly fails to disclose or suggest that her tube member 33 is sized to fulfill this requirement.

Therefore, Applicants believe that claim 13 is patentable over Clayton, and respectfully request reconsideration and withdrawal of the rejection of this claim under 35 U.S.C. § 103(a). Claims 4-5, 7, 9, and 11 depend from and contain all the limitations of independent claim 1, and claims 14-20 and 22-23 depend from and contain all the limitations of independent claim 13. As described above, claims 1 and 13 are believed to be patentable over Clayton. Accordingly, Applicants also respectfully request reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. § 103(a).

Rejection of Claim 27
Under 35 U.S.C. § 103(a) over Hinkle

Claim 27 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hinkle. Claim 27 depends from and contains all the limitations of amended claim 24 which, for the reasons stated above, is believed to be patentable over Hinkle. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 27 under 35 U.S.C. § 103(a).

Rejection of Claims 8 and 21
Under 35 U.S.C. § 103(a) over Clayton and Stevens

Claims 8 and 21 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Clayton in view of U.S. Patent No. 5,810,000 issued to Stevens ("Stevens"). Claims 8 and 21 depend from and contain all the limitations of independent claims 1 and 13, respectively. As described above, claims 1 and 13 are believed to be patentable over Clayton, either alone or in combination with Stevens. Accordingly, reconsideration and withdrawal of the rejection of claims 8 and 21 under 35 U.S.C. § 103(a) is respectfully requested.

Rejection of Claim 30
Under 35 U.S.C. § 103(a) over Hinkle and Stevens

Claim 30 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Hinkle in view of Stevens. Claim 30 depends from and contains all the limitations of independent claim 24 which, for the reasons stated above, is believed to be patentable over Hinkle, either alone or in combination with Stevens. Therefore, Applicants respectfully request reconsideration and withdrawal of this rejection.

Conclusion

In summary, Applicants believe that the claims, as amended, now meet all formal and substantive requirements and that the case is in appropriate condition for allowance. Accordingly, such action is respectfully requested. If a telephone conference would expedite allowance of the case or resolve any further questions, such a call is invited at the Examiner's convenience.

Respectfully submitted,

KAYODE A. WILLIAMS et al.

By _____

David R. Syrowik
Reg. No. 27,956
Attorney/Agent for Applicant

Date: September 17, 2002

BROOKS & KUSHMAN P.C.
1000 Town Center, 22nd Floor
Southfield, MI 48075
Phone: 248-358-4400
Fax: 248-358-3351

Attachment

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claims 1, 12, and 24 have been amended as follows:

1. (Amended) A medical pacifier for delivering gas to a patient, the pacifier comprising:

a nipple member adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough and an outlet opening provided therein; and

a base attached to the nipple member and adapted to remain outside the oral cavity, the base including an inlet opening provided therein and a lumen extending therethrough which is in fluid communication with the conduit of the nipple member, wherein the inlet opening is [adapted to be connected] sized for connection to [an external gas source] a standard breathing tube such that gas can flow through the base and the nipple member for delivery via the outlet opening into the oral cavity of the patient.

12. (Amended) A medical pacifier for delivering anesthetic gas to a patient, the medical pacifier comprising:

a base adapted to remain outside an oral cavity of the patient, the base including a base plate having a concave front surface and a convex rear surface[,];

a connector projecting from the base plate rear surface, the connector including [which includes] an inlet opening provided in a proximal end thereof and a lumen extending therethrough, the proximal end having an outer diameter of approximately 15 mm for compatibly attaching to a standard breathing tube for providing a source of anesthetic gas; and

a nipple member projecting from the base plate front surface and adapted to be received within an oral cavity of the patient, the nipple member having a conduit extending therethrough which is in fluid communication with the lumen and an outlet opening provided in a distal end thereof[,

wherein the inlet opening is adapted to be connected to a source of anesthetic gas,] such that anesthetic gas can flow through the pacifier for delivery via the outlet opening into the oral cavity of the patient.

24. (Amended) A method for delivering gas to a patient, the method comprising:

inserting a medical pacifier into an oral cavity of the patient, the pacifier including a nipple member adapted to be received within the oral cavity and having a conduit extending therethrough and an outlet opening provided therein, and a base attached to the nipple member and adapted to remain outside the oral cavity, the base including an inlet opening provided therein and a lumen extending therethrough which is in fluid communication with the conduit of the nipple member;

connecting a gas source to the inlet opening; and

supplying gas through the base and the nipple member for delivery via the outlet opening exclusively into the oral cavity of the patient.